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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/770,601	01/26/2001	Myra A. Lipis	10276-015002	6880

7590

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EXAMINER

BAKER, ANNE MARIE

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 07/08/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/770,601

Applicant(s)

LIPES ET AL.

Examiner

Anne-Marie Baker

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-- Th MAILING DATE of this communication appears on the cover sheet with the corresponding address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-38 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 26-38 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

The preliminary amendments filed January 26, 2001 (Paper No. 8) and July 16, 2001 (Paper No. 5) have been entered. Claims 1-29 and 39-59 have been cancelled.

Claims 26-38 remain pending in the instant application.

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 26-31, drawn to a method of producing a protein in a subject *in vivo* by introducing into the subject an immunologically privileged cell which expresses the protein, classified in class 424, subclass 93.1.
- II. Claims 32-35, drawn to a transgenic animal expressing at least one protein not normally expressed in intermediate lobe pituitary cells, classified in class 800, subclass 13.
- III. Claims 36-38, drawn to a subject which has an intermediate lobe pituitary cell which expresses a peptide not normally expressed in intermediate lobe pituitary cells, classified in class 800, subclass 8.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II-III are patentably distinct, one from the other, because the inventions are drawn to distinct compositions and materially different methods. The transgenic animal of the invention of Group II is not required for practice of the method of the invention of Group I (i.e., producing a protein in a subject). Although the subject of the invention of Group III can be produced using the method of Group I, the subject can also be produced by methods of making a transgenic animal. Thus, the method

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of the invention of Group I is not specially adapted to making the subject of the invention of Group III. Furthermore, neither the transgenic animal of the invention of Group II nor the subject of the invention of Group III are required for practice of the invention of Group I. Thus, the method of the invention of Group I is patentably distinct from the compositions of the inventions of Groups II and III.

Inventions II and III are patentably distinct, one from the other, because the inventions are drawn to distinct compositions. The transgenic animal of the invention of Group II is structurally, biologically, and functionally distinct from the subject of the invention of Group III. A transgenic animal is fundamentally different from a subject into which genetically modified cells have been introduced. Although Claims 36-38 are broad enough to read on transgenic animals, they also read on animals that do not have a transgene present in every cell, but rather have some heterologous cells present somewhere in the body. The subject of the invention of Group III would not necessarily have the requisite genetic modification in every cell of the body, whereas the transgenic animal would. Subjects that have heterologous cells present in the body are chimeric rather than transgenic. Thus, the transgenic animal of the invention of Group II is patentably distinct from the subject of the invention of Group III.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter and because the searches required for the separate inventions are not coextensive, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of

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inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne-Marie Baker whose telephone number is (703) 306-9155. The examiner can normally be reached Monday through Thursday and alternate Fridays from 10:00 AM to 7:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst, Dianiece Jacobs, whose telephone number is (703) 305-3388.

Anne-Marie Baker, Ph.D.

Anne-Marie Baker
ANNE-MARIE BAKER
PATENT EXAMINER